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Intellectual Property Department
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EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3768	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,671	MASCHKE, MICHAEL	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/24/09 and 2/23/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 11-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (US Pat: 6,394,952) stand alone or in view of Blinkert et al (2003/0197734) or Murphy (2003/0204248).

Regarding claims 11-15, 19-21, and 24, Anderson et al teach systems and methods for medical diagnosis or risk assessment for a patient are provided that is pertinent to the claimed invention. Anderson et al teach these systems and methods are designed to be employed at the point of care, such as in emergency rooms, operating rooms, hospital laboratories and other clinical laboratories, doctor's offices, in the field, or in any situation in which a rapid and accurate result is desired. The systems and methods process patient data, particularly data from point of care diagnostic tests or assays, including immunoassays, chemical assays, nucleic acid assays, colorimetric assays, fluorometric assays, hemiluminescent and bioluminescent assays, electrocardiograms, X-rays and other such tests, and provide an indication of a medical condition or risk or absence thereof [see column 2 lines 14-25]. The systems include

an instrument for reading or evaluating the test data and software for converting the data into diagnostic or risk assessment information. The systems include a test device (this device is used as the control unit, emphasis added), such as a test strip, optionally encased in housing, for analyzing patient samples and obtaining patient data.

The device includes a symbology, such as a bar code which is used to associate identifying information, such as intensity value, standard curves, patient information, reagent information and other such information, with the test device. The reader in the system is optionally adapted to read the symbology [see column 2 lines 28-38]; systems and methods for detecting and measuring levels of a target analyte in a patient sample, analyzing the resulting data, and providing a diagnosis or risk assessment are provided. The systems and methods include an assay device in combination with a reader, particularly a computer-assisted reader, preferably a reflectance reader, and data processing software employing data reduction and curve fitting algorithms [see column 2 lines 65-67 and column 3 lines 1-5], optionally in combination with a trained neural network for accurately determining the presence or concentration of analyte in a biological sample [see column 3 lines 1-20].

The data obtained from the reader then can be further processed by the medical diagnosis system to provide a risk assessment or diagnosis of a medical condition as output and the output can be used as input into a subsequent decision support system, such as a neural network (this is used as a control unit, emphasis added), that is trained to evaluate such data [see column 3 lines 1-20].

Anderson et al teach the reflectance reader is adapted to read a symbology (this refers to an identification code as shown in fig 25, emphasis added) on the test device. The symbology is preferably a bar code which be read in the same manner that the test strip in the device can be read. The reader head scans across a bar code in a stepwise fashion. The data collected from the bar code is transformed into integrated peak information and analyzed as alphanumeric characters, which are related to information related to the particular device and/or test run or other information, including patient information [see column 3 lines 56-66]. The entire procedure may be automated and/or computer-controlled [see column 3 lines 53-54].

Anderson et al also teach a test strip refers to any means on which patient test data or other data is generated, recorded or displayed in a manner that forms an image or from which an image can be generated. Such strips, include, but are not limited to, immunochromatographic test strips, such as lateral flow devices, X-ray films, such as X-rays and films produced from sequencing gels, EKG printouts, MRI results and other such means that generate or from which an image as defined herein can be generated. The strip is preferably adapted for scanning or reading by a reader, preferably the reader provided herein. Although referred to as a "strip", it can be of any shape or geometry, including rectangular, three dimensional, circular, and so forth [see column 6 lines 53-64].

Anderson et al doesn't explicitely mention that the identification information is used to control taking of high energy image.

Applicant discloses that medical adjuvant is for example stents, graft, contrast agent or dye [see column 1 lines 28-30 in the specification].

A reagent is a substance or compound consumed during a chemical reaction solvent catalysts although they are involved in the reaction, are usually not referred to as reactants. Although the terms *reactant* and *reagent* are often used interchangeably, a *reagent* is more specifically "a test substance that is added to a system in order to bring about a reaction or to see whether a reaction occurs". Such a reaction is used to confirm the presence of another substance (emphasis added). A contrast agent or dye is a form of reagent (emphasis added).

However, Anderson et al teach the device includes a symbology, such as a bar code which is used to associate identifying information, such as intensity value, standard curves, patient information, reagent information and other such information, with the test device. The reader in the system is optionally adapted to read the symbology [see column 2 lines 28-38]. Anderson et al teach that conjugated to latex particles containing a blue dye may be used [see column 16 lines 1-5]. Dye is also insertable or injectable (emphasis added).

However, Blinkert et al teach an image of the suggested stent graft is displayed inserted in the graphic of the vessels in a graphic user interface. This allows the physician to evaluate whether the suggested stent graft is sized properly [see 0020].

However, Murphy teaches stent 100 is implanted in heart 62, then in an image 154 of heart 62 generated by system 30, the appearance of stent 100 will be

maintained when heart 62 and stent 100 are shown in display 42, as shown in FIG. 7. [see 0050].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to modify the Anderson et al reference by reading a symbology (or stripe, bar code) of a dye, reagent by a bar code reader or scanner as taught by Anderson et al to control the intensity of an X-ray imaging unit; for the purpose of applying a desired energy of the imaging unit.

One with ordinary skill in the art at the time the invention was made would combine Anderson et with Blinkert et al or Murphy to display a stent and an adjacent region within the object; in order to placing or inserting the stent with great accuracy and precision. Displaying the stent provide visual feedback to the operator as to make necessary modifications.

Regarding claims 16 and 18, all other limitations are taught as set forth by the above teaching.

Anderson et al don't explicitly mention displaying concentration of contrast agent.

However, Anderson et al teach the raw data read from the photodetector is then processed by the control circuit to discern the symbology, such as a bar code pattern, in order to provide information regarding the assay device and/or test run and/or reagents, and/or patient and/or to read the test strip to determine the presence or concentration of analyte in the sample [see column 25 lines 57-60].

The raw reflectance data is then analyzed by the control circuit in accordance with appropriate software control to identify the symbology, such as a bar code or determine the presence or concentration of the analyte in the sample. Where the reader is used to read a bar code associated with the test device, the data collected from the bar code are transformed into integrated peak information and analyzed as alphanumeric characters to provide information about the assay device and/or test run. Where the reader is used to detect an analyte, the data collected from the test strip are compared to a threshold or reference reflectance value to determine the presence or concentration of the analyte. The output can be displayed via an operator interface, or can be output to another computer or apparatus [see column 26 lines 27-40].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to display a concentration of contrast agent or dye; in order to evaluate the image as to adjust a parameter of the imaging unit such as the intensity to enhance visualization of the diagnosed area.

Regarding claims 17 and 22-23, all other limitations are taught a set forth by the above teaching.

Anderson et al don't teach displaying a stent and an adjacent region within the object.

However, Blinkert et al teach an image of the suggested stent graft is displayed inserted in the graphic of the vessels in a graphic user interface. This allows the physician to evaluate whether the suggested stent graft is sized properly [see 0020].

However, Murphy teaches FIG. 3 shows an image 54 rendered on display 42 of system 30 of patient P. Image 54 shows a beam hardened artefact 52 as it is implanted inside a coronary artery 58 inside a heart 62 of patient P. The area identified as beam hardened artefact 52 is an inaccurate reproduction of stent 50 as it is implanted inside artery 58. The beam hardening artefact 52 is created by the material of stent 50. Accordingly, system 30 is of limited value in performing post-operative evaluations of stent 50 and for determining whether any restenosis has occurred of coronary artery [see 0048].

FIG. 6 shows a medical device in accordance with an embodiment of the invention as a stent 150. Stent 150 from outward appearances is substantially the same as prior art stent 50, and indeed, in the present embodiment is designed to provide substantially the same mechanical and therapeutic functionality as prior art stent 50. However, in contrast to prior art stent 50, stent 150 is made from a material that has a selected radio-opacity such that the appearance of stent 150 is preserved when stent 150 is exposed to the imaging beam of system 30 and presented on display 42. Thus, when stent 100 is implanted in heart 62, then in an image 154 of heart 62 generated by system 30, the appearance of stent 100 will be maintained when heart 62 and stent 100 are shown in display 42, as shown in FIG. 7. Since image 154 has no beam hardened artefacts, it is now possible to examine the lumen of artery 52 surrounding stent 100, and thereby allow for an examination thereof for restenosis [see 0050].

Therefore, one with ordinary skill in the art at the time the invention was made would have been motivated to combine the Anderson et al and references by displaying a stent and an adjacent region within the object; in order to placing or inserting the stent with great accuracy and precision. Displaying the stent provide visual feedback to the operator as to make necessary modifications.

Response to Arguments

3. Applicant's arguments with respect to claims 11-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768